Remarks

Claims 1-31 are pending in this application. Claims 1 and 12 have been amended, and no claims have been added or canceled. Reconsideration and reexamination of this application are respectfully requested in light of the above amendments and the following remarks.

Allowed Claims

Applicants appreciate the Examiner's indication that claims 24-31 have been allowed.

Rejection of Claims 1-3, 6, and 10
Under 35 U.S.C. § 102(e) Over Clayton

Claims 1-3, 6, and 10 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,197,044 issued to Clayton ("Clayton"). In response, Applicants have amended claim 1 to more particularly point out and distinctly claim the subject matter of the invention.

Claim 1 now recites that "the inlet opening is sized for *secure* connection with a standard breathing tube" (emphasis added; *see* p. 4, lines 10-12; p. 8, lines 18-31). Applicants assert that Clayton does not disclose or suggest this feature of Applicants' invention. The Examiner states that "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art" and that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim" (Final Office Action, Page 2, ¶2). Applicants assert that Clayton's disclosed pacifier structure **is not** capable of forming a secure connection with a standard breathing tube, and therefore does not anticipate Applicants' claimed invention for the reasons explained below.

As is known to those skilled in the art, breathing tubes are required to have standard U.S. and international dimensions. In the United States, the dimension of 15 mm for

breathing tubes is mandated by the Food and Drug Administration under ASTM Standard F1054-87. As such, the inlet opening of Applicants' pacifier is specifically sized for secure connection with a standard breathing tube, such that an anesthesia breathing circuit can be quickly and easily attached to the pacifier with a tight seal that prevents anesthesia gas from escaping at the interface (*see* p. 8, lines 18-31).

In contrast to Applicants' invention, Clayton is directed to a pacifier used to aid introduction of a feeding or medication tube into the oral cavity of a patient for administering fluids. Clayton discloses that her pacifier may be used with a gavage tube feeding system, wherein the gavage tube is threaded through the lumen 18 of the pacifier tube member 33, into the oral cavity, and subsequently down into the patient's esophagus to the stomach. Clayton does not disclose or suggest that tube member 33 has the specific sizing necessary for secure connection with a standard breathing tube as in Applicants' claimed invention. Rather, Clayton states:

> "Tube member lumen 18 is a small diameter, hollow lumen, which is capable of removably receiving a small diameter tube or the like. In a preferred embodiment, the lumen is sized to receive a gavage feeding tube, and more preferably a number 5 or a number 8 gavage tube."
>
> (*see Clayton*, col. 4, lines 29-34)

Number 5 (i.e., 5 French) and number 8 (i.e., 8 French) size tubes translate to metric diameters of 1.67 mm and 2.7 mm, respectively. Consistent with the choice of these feeding tube sizes as her preferred embodiment, Clayton indicates that the size of her pacifier, and therefore tube member 33, "can be made appropriate for micro-preemies, term infants, and pediatrics and still remain within the scope of the present invention" (*see Clayton*, col. 3, line 66 - col. 4, line 2). Clearly, the outer diameter of Clayton's tube member 33 need only be of sufficient width to accommodate tubes having diameters on the order of 2-3 mm. There is no reason to believe that a 15 mm outer diameter for tube member 33, as is required for a secure connection with a standard breathing tube, would ever be necessary or contemplated in the scope of Clayton's invention.

Accordingly, Applicants believe that claim 1 is patentably distinguishable over Clayton, and respectfully request reconsideration and withdrawal of the rejection of this claim and its corresponding dependent claims under 35 U.S.C. § 102(e).

Rejection of Claims 4-5, 7, 9, and 11
Under 35 U.S.C. § 103(a) Over Clayton

Claims 4-5, 7, 9, and 11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton. Claims 4-5, 7, 9, and 11 depend from and contain all the limitations of independent claim 1 which, for the reasons stated above, is believed to be patentably distinguishable over Clayton. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. § 103(a).

Rejection of Claims 12-20 and 22-23
Under 35 U.S.C. § 103(a) Over Clayton and Despotis

Claims 12-20 and 22-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of U.S. Patent No. 4,790,327 issued to Despotis ("Despotis"). Applicants respectfully traverse this rejection for the reasons stated below.

Independent claim 12 recites that the connector proximal end has "an outer diameter of approximately 15 mm for compatibly attaching to a standard breathing tube" (*see* p. 4, lines 10-12; p. 7, lines 23-30). The Examiner asserts that Clayton's connector is adapted to be connected to a source of anesthetic gas (Final Office Action, Page 5, ¶17). For the reasons stated above with reference to claim 1, Applicants respectfully disagree with this characterization of Clayton, and assert that Clayton does not disclose or suggest that her pacifier tube member has the specific sizing necessary to compatibly attach to a standard breathing tube in Applicants' claimed invention.

The Examiner does admit that Clayton fails to specifically teach the 15 mm connector dimension disclosed and claimed by Applicants, but asserts that Clayton instead teaches receiving a medication tube, where "a breathing tube constitutes a medication tube" (Final Office Action, Page 5, ¶17). Applicants respectfully disagree with this characterization. Clayton states that:

> "In operation, as shown in FIG. 4, pacifier assembly 10 may be used with a gavage feeding system, which includes a gavage tube 30 and a gavage container 60. Container 60 may be filled with a nutritive fluid, such as formula or breast milk. Optionally, tube 30 may be connected to a reservoir 60 containing medicine, or the like, or a viscous solution including charcoal, barium, vitamins, and lipids."
>
> (*see Clayton*, col. 4, line 66 - col. 5, line 5).

Clearly, the medication tube disclosed by Clayton is not synonymous with a standard breathing tube as is known to those skilled in the art. Clayton does not disclose or suggest the administration of medicine in any other form than that described above, and certainly does not disclose or suggest delivery of gas via the medication tube.

Furthermore, Clayton's disclosed method of providing medication is the same as that for feeding, namely threading one end of the tube through the pacifier and down the patient's throat (*see Clayton*, col. 3, lines 33-42), wherein the other end of the tube is connected to a reservoir containing liquid medication. This is in direct contrast to Applicants' claimed invention, since breathing tubes are never introduced into the patient's throat, but instead remain external to the body. Likewise, Clayton's invention would not function properly if the feeding/medication tube remained external to the body, as this configuration would not allow food or medicine to be introduced directly into the stomach.

The Examiner asserts that it would have been obvious to combine Clayton and Despotis and make Clayton's tube member a standard size (i.e., 15 mm) to allow connection to a standard breathing tube (Final Office Action, Page 6, ¶17). Applicants respectfully disagree, and assert that there is no motivation or suggestion to combine the Clayton and Despotis references. Clayton is directed only to providing liquid food or medication to a patient via a tube threaded through the pacifier and down the patient's throat, and does not disclose or suggest providing gas to a patient. Furthermore, Clayton teaches away from Applicants' claimed invention, disclosing only a feeding/medication tube that is inserted through the pacifier and down the patient's throat to deliver liquid to the stomach, with no teaching or suggestion of a breathing tube connecting externally to the pacifier for the delivery

of gas to the patient. Lastly, Clayton does not recognize the problem solved by Applicants' invention, namely providing a pacifier having a connector specifically sized to be securely connected to a standard breathing tube for delivering gases to a patient. Applicants have explained that a specific pacifier construction is required for suitable connection to a standard breathing tube and circuit, and Clayton clearly fails to realize the necessity of a tube member 33 sized to fulfill this requirement.

Accordingly, Applicants believe that claim 12 is patentably distinguishable over Clayton in view of Despotis, and reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

Turning now to independent claim 13, Applicants recite the combination of a breathing circuit and a medical pacifier connected to the breathing circuit, where the pacifier includes an inlet opening adapted to be connected to the inlet tube (i.e., standard breathing tube) of the breathing circuit. The Examiner asserts that Clayton also discloses an inlet opening which is adapted to be connected to an inlet tube (Final Office Action, Page 6, ¶18). Again, Applicants respectfully disagree. For the reasons stated above with reference to claims 1 and 12, Applicants assert that Clayton provides no disclosure or suggestion that her pacifier tube member is specifically sized for connection to a standard breathing tube.

The Examiner admits that Clayton fails to specifically teach a breathing circuit and an inlet tube. However, the Examiner asserts that Clayton does disclose the use of the pacifier to administer medications through the tube, and that it would be obvious to provide a breathing circuit as a form of administering medicament to the patient (Final Office Action, Page 6, ¶18). Applicants respectfully disagree. For the reasons stated above with reference to claim 12, Applicants assert that Clayton only discloses providing medication in fluid form using a gavage feeding system. There is no teaching or suggestion in Clayton to provide gases to the patient or to attach her pacifier to a breathing circuit, nor is her pacifier configured to even be capable of attachment to an inlet tube of a breathing circuit.

Therefore, claim 13 is believed to be patentably distinguishable over the combination of Clayton and Despotis, and Applicants respectfully request reconsideration and withdrawal of the rejection of this claim, and corresponding dependent claims 14-20 and 22-23, under 35 U.S.C. § 103(a).

Rejection of Claim 8
Under 35 U.S.C. § 103(a) Over Clayton and Stevens

Claim 8 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of U.S. Patent No. 5,810,000 issued to Stevens ("Stevens"). Claim 8 depends from and contains all the limitations of independent claim 1 which, for the reasons stated above, is believed to be patentably distinguishable over Clayton, either alone or in combination with Stevens. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 8 under 35 U.S.C. § 103(a).

Rejection of Claim 21
Under 35 U.S.C. § 103(a) Over Clayton, Despotis, and Stevens

Claim 21 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of Despotis and Stevens. Claim 21 depends from and contains all the limitations of independent claim 12 which, for the reasons stated above, is believed to be patentably distinguishable over Clayton and Despotis, either alone or in combination with Stevens. Therefore, Applicants also respectfully request reconsideration and withdrawal of this rejection.

Conclusion

In summary, Applicants believe that the claims, as amended, now meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1 and 12 have been amended as follows:

1. (Twice Amended) A medical pacifier for delivering gas to a patient, the pacifier comprising:

a nipple member adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough and an outlet opening provided therein; and

a base attached to the nipple member and adapted to remain outside the oral cavity, the base including an inlet opening provided therein and a lumen extending therethrough which is in fluid communication with the conduit of the nipple member, wherein the inlet opening is sized for secure connection [to] with a standard breathing tube such that gas can flow through the base and the nipple member for delivery via the outlet opening into the oral cavity of the patient.

12. (Twice Amended) A medical pacifier for delivering anesthetic gas to a patient, the medical pacifier comprising:

a base adapted to remain outside an oral cavity of the patient, the base [including a base plate] having a generally concave front surface and a generally convex rear surface;

a connector projecting from the base [plate] rear surface, the connector including an inlet opening provided in a proximal end thereof and a lumen extending therethrough, the connector proximal end having an outer diameter of approximately 15 mm for compatibly attaching to a standard breathing tube for providing a source of anesthetic gas; and

a nipple member projecting from the base [plate] front surface and adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough which is in fluid communication with the lumen and an outlet opening provided in a distal end thereof such that anesthetic gas can flow through the pacifier for delivery via the outlet opening into the oral cavity of the patient.

Attachment